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EXAMINER	
MESSERSMITH, ERIC	

ART UNIT	PAPER NUMBER
3735	

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11/23/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/584,179	CRABTREE ET AL.
	Examiner	**Art Unit**
	ERIC MESSERSMITH	3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/01/2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-23,27-35,43 and 44* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-23,27-35,43 and 44* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *23 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/19/2011*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 35 is objected to because of the following informalities: there should be a semicolon inserted after the second clause. Appropriate correction is required.

All other objections are withdrawn.

Claim Rejections - 35 USC § 112

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 22, the limitation "the indicator" is recited in the first line of the claim. It is unclear whether "the indicator" is "a quantitative indicator" recited in claim 17 or some other indicator.

As to claim 44, it is unclear whether the claim is directed to an apparatus or a method. For purpose of examination on the merits, however, it is understood to be a method claim.

Claim Rejections - 35 USC § 101

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 35 and 44 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Regarding claims 35 and 44, courts have given the "process" category recited in 35 USC 101 a specialized and limited meaning. *See, e.g., Bilski v.*

Kappos, 130 S. Ct. 3218, 561 US __, 177 L. Ed. 2d 792 (2010). These decisions adhere to the well-settled view that abstract ideas are *per se* patent ineligible subject matter. One test for determining whether a claim method recites an abstract idea is whether the method is tied to a particular machine or apparatus or transforms a particular article into a different state or thing. Because the machine or transformation must impose meaningful limits on the method claim's scope, a mere nominal recitation of a specific machine or a particular transformation in an insignificant step is not sufficient to pass the test. Because applicants' claims fail to recite a specific apparatus in carrying out any of the aforementioned method steps, they fail to be patent-eligible processes.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claim 44 is rejected under 35 U.S.C. 102(b) as being anticipated by an article entitled "Influence of different types of recovery positions on perfusion indices of the forearm" by Rathgeber et al (hereinafter "Rathgeber").

As to claim 44, Rathgeber discloses analyzing light reflected from a limb of a subject when the subject is in a first posture to determine a quantitative value for blanching of the limb in the first posture (see section 2.2 on pp 14-15-- blanching of the skin is indicative of a lack of perfusion); and analyzing light reflected from the limb of the subject when the subject is in a second posture to determine a quantitative value for blanching of the limb in the second posture (see section 2.2 on pp 14-15).

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-23 and 27-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rathgeber in view of US 2003/0163033 A1 (Dekker).

As to claim 1, Rathgeber discloses a circuitry configured to detect a signal dependent upon an arterial blood volume in the limb of the subject when the subject is in a first posture and also when the subject is in a second posture, different to the first posture (see section 2.2 on pp 14-15), but does not explicitly disclose the circuitry being a pre-processing circuitry and does not explicitly disclose a processing circuitry configured to calculate a quantitative indicator that is dependent upon a ratio of the detected signal for the first posture to the detected signal for the second posture. Rathgeber discloses the pre-processing and processing circuitry configured to determine these values, but does not do so explicitly. Rathgeber only discloses that the circuitry is taken from a modified pulse oximeter which is well-known for containing such pre-processing and processing circuitry, as evidenced below.

For example, Dekker discloses pre-processing circuitry configured to detect a signal dependent upon an arterial blood volume in the limb of the subject when the subject is in a first posture and also when the subject is in a second posture (see para [0032], Fig 1, element 23 and Fig 4, element 212 the filter will pre-process a signal at any posture); a processing circuitry configured to calculate a quantitative indicator that is dependent upon the ratio of the signal for the first and second posture (see para [0019], [0041],[0052] and [0056] -- processor for calculating a ratio of ratios shows a capability of calculating a ratio of any input, such as the inputs suggested by Rathgeber) and means for separating the parameter into a first component

and a second component (para [0021] to [0022], [0032] and [0056]); Fig 1, element 23 and Fig 4, element 212 -- filter separates AC and DC components of signal). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the circuitry configured to detect a signal dependent upon an arterial blood volume in the limb of the subject when the subject is in a first and second posture as disclosed by Rathgeber with the processing circuitry disclosed by Dekker, since Rathgeber suggests the use of such a device (a pulse oximeter) and since such a combination would automate the calculation disclosed by Rathgeber.

As to claims 2, Rathgeber further teaches that the quantitative indicator (PPI) is directly proportional to the ratio of the signal for the first posture to the signal for the second posture (see p 15 -- (PPI)=(AC/DC) and Fig 6 and accompanying text).

As to claim 3, Rathgeber further discloses wherein the detected signal dependent upon the arterial blood volume of the limb is a pulsating component of a measured parameter, the measured parameter being dependent upon the blood volume in the subject's limb (see Fig 5).

As to claim 4, Rathgeber further teaches that the calculation of the quantitative indicator is additionally dependent upon the ratio of a non-pulsating component of the measured parameter for the second posture to a non- pulsating component of the measured parameter for the first posture (see Fig 6 and accompanying text -- PPI change as percentage of supine in various positions).

As to claim 5, Rathgeber further teaches that the quantitative indicator is directly proportional to the ratio of the non-pulsating component of the measured parameter for the second posture to the non-pulsating component of the measured parameter for the first posture (see Fig 6 and accompanying text -- PPI change as percentage of supine in various positions).

As to claim 6, Rathgeber further discloses at least one sensor configured to measure a parameter indicative of the blood volume of the limb when the subject is in a first posture and to measure the parameter when the subject is in a second posture (see p. 14, Section 2.2-- pulse oximeter configured to assess quantitative photoplethysmographic data). Dekker further discloses circuitry configured to isolate a pulsating component of the measured parameter (see Fig 1, element 212 and para [0056])

As to claims 7, 14 and 31, Rathgeber does not disclose wherein the limb is a foot. Rathgeber does disclose the limb being a hand (p 15, right column, line 4-5). Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets limitations of the claim. Here, the finger pulse oximeter is capable of performing the intended use.

As to claims 8-9, 15-16 and 32, Rathgeber further teaches wherein the position of the limb is changed between the first posture and the second posture, a portion of the limb in the first posture being at a first elevation and a portion of the limb in the second position being at a second position (Fig 1-4, 6 and accompanying text).

As to claim 10, 23 and 33-34, Rathgeber discloses the discloses the measured parameter being measured by pulse oximetry (which inherently is of fixed intensity) and the ratio of the signal for the first posture to the signal for the second posture reduces subject dependent influences such as variable light absorption of the blood and tissue in the limb for different subjects (p 15, right column, line 4-5 --ratio of the signals in the first and second postures

inherently meets this intended use).but is silent as to whether measurement is the intensity of light reflected from the limb. Dekker teaches that pulse oximeters are either reflectance or transmittance types (para [0003]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to try a pulse oximeter that measures the intensity of light reflected from the limb, since there are only a finite number of solutions possible.

As to claim 11, Rathgeber discloses detecting a signal dependent upon an arterial blood volume in the limb of the subject when the subject is in a first posture (see section 2.2 on pp 14-15); detecting a signal dependent upon the arterial blood volume in the limb of the subject when the subject is in a second posture, different to the first posture (see section 2.2 on pp 14-15). Rathgeber discloses the use of a device with a processor (e.g., a pulse oximeter) but does not explicitly disclose the step of using a processor to calculate a quantitative indicator that is dependent upon a ratio of the signal for the first posture to the signal for the second posture.

However, Dekker discloses a processor that is used to calculate a ratio of one signal to another (see para [0019], [0041],[0052] and [0056] -- processor for calculating a ratio of ratios shows a capability of calculating a ratio of any input, such as the inputs suggested by Rathgeber). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the detecting an arterial-blood-volume-dependent signal disclosed by Rathgeber with the processing means and separating means disclosed by Dekker, since Rathgeber suggests the use of such a device (a pulse oximeter) and since such a combination would automate the calculation disclosed by Rathgeber.

Regarding claims 12-13, Rathgeber discloses the step of measuring a parameter that is dependent upon the blood volume in the subject's limb and further discloses wherein the

quantitative indicator is additionally dependent upon the ratio of the non- pulsating component of the measured parameter for the second posture to the non-pulsating component of the measured parameter for the first posture. (see section 2.2 on pp 14-15) but does not specifically disclose the step of isolating, as the signal, a pulsating or non-pulsating component of the measured parameter. Dekker discloses the step of isolating, as the signal, pulsating and non-pulsating components of the measured parameter (para [0018]-[0019], [0022]). It would have been obvious to one of ordinary skill in art at the time the invention was made to combine the steps disclosed by Rathgeber with the signal isolating step disclosed by Dekker, since isolating the pulsating and/or non-pulsating components allows arterial and/or venous flow and oxygen saturation to be independently monitored.

As to claim 17, Rathgeber discloses: a sensor configured to measure a parameter dependent upon a blood volume in a limb of the subject when the subject is in a first posture and also when the subject is in a second posture, different to the first posture (see section 2.2 on pp 14-15). Rathgeber discloses a formula for calculating a quantitative indicator that is dependent upon the ratio of the signal for the first posture to the signal for the second posture (see p 15 -- (PPI)=(AC/DC) and Fig 6 and accompanying text) and indicates that the AC and DC component of the signal are to be separated (see p. 15 -- PVI = I_o/DC) but does not explicitly disclose the particular circuitry configured to separate the parameter into a first component and a second component and does not disclose a processor configured to calculate a quantitative indicator wherein the calculation takes as inputs the first component of the parameter for the first posture and the first component of the parameter for the second posture. Rathgeber discloses the circuitry for separating signals and processing circuitry configured to determine these values, but does not

do so explicitly. Rathgeber only discloses that the circuitry is taken from a modified pulse oximeter which is well-known for containing such circuitry and processing circuitry, as evidenced below.

For example, Dekker discloses circuitry configured to separate the parameter into a first component and a second component (see para [0032] and [0056], Fig 1, element 23 and Fig 4, element 212); and a processor configured to calculate a quantitative indicator wherein the calculation takes as inputs the first component of the parameter for the first posture and the first component of the parameter for the second posture (see para [0019], [0041],[0052] and [0056] -- processor for calculating a ratio of ratios shows a capability of calculating a ratio of any input, such as the inputs suggested by Rathgeber). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the sensor for detecting an arterial-blood-volume-dependent signal disclosed by Rathgeber with the processing means and separating means disclosed by Dekker, since Rathgeber suggests the use of such a device (a pulse oximeter) and since such a combination would automate the calculation disclosed by Rathgeber.

As to claim 18, Rathgeber discloses the first component is a pulsating component and the second component is non-pulsating component (see p 15 -- (PPI)=(AC/DC)).

As to claim 19, Rathgeber discloses the indicator is dependent upon the ratio of the first component of the parameter for the first posture to the first component of the parameter for the second posture (Fig 6 and accompanying text -- y-axis shows the ratio).

As to claim 20, Rathgeber discloses the indicator is directly proportional to the ratio of the first component of the parameter for the first posture to the first component of the parameter for the second posture (see p 15 -- (PPI) = (AC/DC) and Fig 6 and accompanying text).

As to claim 21, Rathgeber discloses wherein the indicator is dependent upon the ratio of the second component of the parameter for the second posture to the second component of the parameter for the first posture (see p 15 -- (PPI)=(AC/DC) and Fig 6 and accompanying text).

As to claim 22, Rathgeber discloses wherein the indicator is directly proportional to the ratio of the second component of the parameter for the second posture to the second component of the parameter for the first posture (see p 15 -- (PPI)=(AC/DC) and Fig 6 and accompanying text).

As to claim 27, Rathgeber discloses measuring a parameter dependent upon a blood volume in a limb of a subject when the subject is in a first posture and also when the subject is in a second posture, different to the first posture (see section 2.2 on pp 14-15); separating the parameter into a first component and a second component (see p. 15 -- AC and DC components are separated in order to calculate the quantity PVI = I_o/DC). Rathgeber does not explicitly disclose the step of using a processor to calculate a quantitative indicator which takes as inputs the first component of the parameter at a first posture and the first component of the parameter at a second posture. Rathgeber does, however, disclose using the processor that is found in a pulse oximeter, which is well-known for calculating such inputs, as evidenced below.

For example, Dekker discloses the step of using a processor to calculate a quantitative indicator wherein the calculation takes as inputs the first component of the parameter for the first posture and the first component of the parameter for the second posture (see para [0019],

[0041],[0052] and [0056] -- processor for calculating a ratio of ratios shows a capability of calculating a ratio of any input, such as the inputs suggested by Rathgeber). It would have been obvious to one of ordinary skill in the art to combine the step of measuring a parameter dependent upon a blood volume of a subject when the subject is at a first and second posture as taught by Rathgeber with the step of using a processor to calculate a quantitative indicator as taught by Rathgeber, since Rathgeber suggests the use of such a calculation and since such a combination would automate the calculation disclosed by Rathgeber.

As to claim 28, Rathgeber discloses the first component is a pulsating component and the second component is non-pulsating component (see p 15 -- (PPI)=(AC/DC)).

As to claim 29, Rathgeber discloses wherein the indicator is dependent upon the ratio of the first component of the parameter for the first posture to the first component of the parameter for the second posture (Fig 6 and accompanying text -- y-axis shows the ratio).

As to claim 30, Rathgeber discloses a sensor configured to measure a parameter indicative of a blood volume of the limb when the subject is in a first posture and to measure the parameter when the subject is in a second posture (see section 2.2 on pp 14-15) and Rathgeber discloses a formula for calculating a quantitative indicator that is dependent upon the ratio of the signal for the first posture to the signal for the second posture (see p 15 -- (PPI)=(AC/DC) and Fig 6 and accompanying text) and indicates that the variables, AC and DC, of the signal are to be isolated (see p. 15 -- PVI = I_o/DC) but does not explicitly disclose the particular circuitry configured to isolate a variable value of the measured parameter or a processor configured to determine a quantitative indicator that is dependent upon a ratio of the isolated variable value of the parameter measured for the first posture to the isolated variable value of the parameter

measured for the second posture. Rathgeber only discloses that the circuitry and processor is taken from a modified pulse oximeter, which is well-known for containing circuitry and a processor, as evidenced below.

Dekker discloses a circuitry configured to isolate a variable value of a measured parameter (see para [0032], Fig 1, element 23 and Fig 4, element 212) and a processor configured to determine a quantitative indicator that is dependent upon a ratio of the isolated variable value of the parameter measured for the first posture to the isolated variable value of the parameter measured for the second posture (see para [0019], [0041],[0052] and [0056] -- processor for calculating a ratio of ratios shows a capability of calculating a ratio of any input, such as the inputs suggested by Rathgeber). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the sensor for detecting an arterial-blood-volume-dependent signal disclosed by Rathgeber with the circuitry and processor disclosed by Dekker, since Rathgeber suggests the use of such a device (a pulse oximeter) and since such a combination would automate the calculation disclosed by Rathgeber.

As to claim 35, Rathgeber discloses measuring a parameter indicative of a blood volume of the limb when the subject is in a first posture and isolating a variable value of the parameter measured for the first posture; measuring the parameter indicative of the blood volume of the limb when the subject is in a second posture (see section 2.2 on pp 14-15); isolating a time-variable value of the parameter measured for the second posture (see p. 15 -- AC is a time variable value is separated from the DC component in order to calculate the quantity PVI = I_o/DC) but does not disclose the step of using an apparatus to determine a quantitative indicator

that is dependent upon the ratio of the time-variable value of the parameter measured for the first posture to the time-variable value of the parameter measured for the second posture.

However, Dekker discloses a processor that is used to calculate a ratio of one signal to another (see para [0019], [0041],[0052] and [0056] -- processor for calculating a ratio of ratios shows a capability of calculating a ratio of any input, such as the inputs suggested by Rathgeber). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the detecting an arterial-blood-volume-dependent signal disclosed by Rathgeber with the processing means and separating means disclosed by Dekker, since Rathgeber suggests the use of such a device (a pulse oximeter) and since such a combination would automate the calculation disclosed by Rathgeber.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rathgeber Dekker and further in view of an article entitled "The influence of changes in blood flow on the accuracy of pulse oximetry in humans" by Vegfors et al. (hereinafter "Vegfors").

As to claim 43, Rathgeber discloses a first sensor configured to measure a first optical parameter dependent upon a blood volume when a subject is in a first posture and also when the subject is in a second posture (see section 2.2 on pp. 14-15) but does not disclose circuitry configured to calculate one or more quantitative indicators based on the first parameter for the first posture, the first parameter for the second posture. However, Dekker discloses circuitry that is configured to calculate a quantitative indicator based on a first parameter for a first posture and the first parameter for a second posture (see para [0019], [0041],[0052] and [0056] -- processor for calculating a ratio of ratios shows a capability of calculating a ratio of any input, such as the inputs suggested by Rathgeber). It would have been obvious to one of ordinary skill in the art at

the time the invention was made to combine the detecting an arterial-blood-volume-dependent signal disclosed by Rathgeber with the processing means and separating means disclosed by Dekker, since Rathgeber suggests the use of such a device (a pulse oximeter) and since such a combination would automate the calculation disclosed by Rathgeber.

Neither Rathgeber nor Dekker disclose a second sensor configured to measure a second optical parameter, different to the first optical parameter, when the subject is in the first posture and also when the subject is in the second posture or circuitry configured to calculate a quantitative indicator based on the second parameter for the first posture, and the second parameter for the second posture. However, Vegfors discloses a second sensor configured to measure a second optical parameter, different to the first optical parameter (see p. 346, Patients and Methods -- laser Doppler probe is attached to same hand as pulse oximeter). A quantitative indicator of blood flow is outputted from the laser Doppler probe, a value is calculated, but it is not calculated by a processor (see p. 346-347 -- mean flow and statistical analysis are calculated). It would have been obvious to one of ordinary skill in the art to modify the circuitry disclosed by Rathgeber and Dekker such that the calculations performed by hand in Vegfors are performed by the circuitry of Rathgeber and Dekker so that the calculations are automated. One would have been motivated to combine the types of sensors disclosed by Rathgeber based on the teachings of Vegfors, which first, explicitly disclosed said combination, and second, teach that a laser Doppler flow meter can be used verify that the decreases in perfusion recorded by the pulse oximeter in Rathgeber are caused by a reduction in flow and not by an instrument error.

Response to Arguments

8. Applicant's arguments filed August 1, 2011 have been fully considered but they are not persuasive.

Applicants argue that the ratio calculated by Rathgeber is not the same as the ratio determined by the invention of claim 11 because the photoplethysmographic pulsatility index (PPI) disclosed by Rathgeber is a ratio of a long term average of a detected signal in a first posture to a long term average of a detected signal in a second posture. However, no particular quantitative indicator is found in the claims. Because the claims are directed only to *a* quantitative indicator, the indicator depicted by Rathgeber in Figure 6 reads on this limitation. Similarly, the length of time between measurements or that they are averaged is similarly not relevant to the analysis of the claims in view of the prior art. There is nothing in claims limiting the calculation of a "quantitative indicator" in any way, other than it be a ratio of a signal in a first posture to a signal in a second posture. Thus, Applicant appears to acknowledge that the prior art reference meets the limitation of claim 1. *See Applicant Remarks* at 11 ("The PPI is dependent on a ratio of a long term (5 minute) average of a detected signal in a first posture to a long term (5 minute) average of a detected signal in a second posture."). While the claims must be viewed in light of the specification, Examiner should not read limitations from the specification into the claims.

Applicants further argue that there is no indication of how the AC signal might be separated from the DC signal other than by a clinician observing the plot of Figure 5 disclosed by Rathgeber. However, by its name, the index disclosed by Rathgeber is the "pulsatility index," which is concerned with the time-varying component of the pulse (i.e., AC component). An

examination of the Applicant's specification at page 17 shows that the calculation performed to determine the ratio is given as

$$R = \frac{I(1)_{AC} / I(1)_{DC}}{I(2)_{AC} / I(2)_{DC}}$$

where $I(1)_{AC}$ and $I(2)_{AC}$ are the AC component of the intensity of light detected by a PPG sensor at the first and second postures, respectively and $I(1)_{DC}$ and $I(2)_{DC}$ are the DC component of the intensity of light detected by a PPG sensor at the first and second postures, respectively. This is the same calculation as Rathgeber's PPI calculation depicted in Figure 6, where PPI = AC/DC. Each of the different postures is expressed as a ratio of the supine position. Therefore, each ratio described by Rathgeber is

$$R = \frac{I(Position)_{AC} / I(Position)_{DC}}{I(Supine)_{AC} / I(Supine)_{DC}}$$

where *I(Position)* is defined as one of the various recovery positions disclosed by Rathgeber.

Applicants' assertion that Rathgeber does not separate the DC component from the AC component of the signal is similarly not persuasive, since that is the only way to calculate PVI, which is equal to the quantity I_o/DC, is to isolate the DC component and, by extension, the AC component of the signal.

Applicants assert that Rathgeber is not responsive to a posture change, but this argument appears to misinterpret the reference. Subjects were placed between a first posture of two different postures. Then the subjects were placed in the second posture of two difference postures. However, before and between each measurement, subjects were placed in the supine

position, which is also a third posture. Thus, each measurement was made in view of a posture change from supine posture to a different posture, resulting in a change in posture. That the quantitative indicator measures a **response to postural change** is not recited in the claims.

Applicant further asserts that Rathgeber and Dekker are drawn to unrelated fields and that a person of ordinary skill in the art would not seek to combine their teachings. However, Rathgeber and Dekker each present applications of photoplethysmography in general and pulse oximeters in particular as applied in the field of medicine. Rathgeber is primarily concerned with assessing capillary perfusion, the delivery of arterial blood to the tissue bed. Pulse oximetry is also used to assess perfusion. Therefore, these are related technologies.

Applicant further asserts that there would be no reason to automate the teaching of Rathgeber. This is not persuasive. Automatically calculating the ratio would save a tremendous amount of time and would also reduce computational errors by relying on an automatic determination of this value.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC MESSERSMITH whose telephone number is (571)270-7081. The examiner can normally be reached on Mon-Fri 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MIRANDA LE can be reached on (571) 272-4112. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ERIC MESSERSMITH/
Examiner, Art Unit 3735
11/15/2011

/Patricia Mallari/
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